201-14282

Mary-Beth Weaver
02/07/2003 07:30 AM

To: NCIC HPV@EPA
cc:
Subject: SOCMA's Chlorobenzene Producers Association (CPA) Response to EPA's Comments on Our HPV Submission

Mary Beth Weaver
OPPT Docket Manager (Contractor)
202-566-0278
----- Forwarded by Mary-Beth Weaver/DC/USEPA/US on 02/07/2003 07:30 AM -----

Ed Kordoski <Kordoski@SOCMA.com> on 02/06/2003 03:30:52 PM

To: "oppt.ncic@epa.gov" <'oppt.ncic@epa.gov'>, "chem.rtk@epa.gov" <'chem.rtk@epa.gov'>
cc: Ed Kordoski <Kordoski@SOCMA.com>, Jessica Ross <Rossj@SOCMA.com>, Rod Gerwe <r.gerwe2@verizon.net>, Laurie Deyo <ldeyo@preferred.com>

Subject: SOCMA's Chlorobenzene Producers Association (CPA) Response to EPA's Comments on Our HPV Submission

Chlorobenzene Producers Association

1850 M Street NW

Suite 700

Washington, DC 20036-5810

February 6, 2003

Via U.S. Mail and Internet Submission

Christine Todd Whitman, Administrator
U.S. Environmental Protection Agency
Post Office Box 1473
Merrifield, VA 22116

Attn: Chemical Right-to-Know Program; HPV Challenge Program

The Synthetic Organic Chemical Manufacturers Association's (SOCMA) Chlorobenzene

Producers Association (CPA) is responding within the allotted 90 days to EPA's comments on our robust summaries and test plan for the chlorobenzenes category. The EPA's comments and questions were contained in a letter to CPA from Mr. Oscar Hernandez, Director, Risk Assessment Division, dated November 7, 2002. The chlorobenzenes category represents four chlorinated benzenes: monochlorobenzene (CAS # 108-90-7), 1,2-dichlorobenzene (CAS # 95-50-1), 1,3-dichlorobenzene (CAS # 541-73-1), and 1,2,3-trichlorobenzene (CAS # 87-61-6), but also includes data on the structural analogs: 1,4-dichlorobenzene (CAS # 106-46-7) and 1,2,4-trichlorobenzene (CAS # 120-82-1). The HPV Challenge CPA robust summaries and test plan were posted for public comment on the ChemRTK HPV Challenge Program Website on April 2, 2002.

The edited and enclosed final HPV document is a compilation of five individual documents: Test Plan and Category Justification for the Chlorobenzenes Category; Robust Summaries and Repository of Knowledge for CAS No. 108-90-7 (monochlorobenzene); Robust Summaries and Repository of Knowledge for CAS No. 95-50-1 (1,2-dichlorobenzene); Robust Summaries and Repository of Knowledge for CAS No. 541-73-1 (1,3-dichlorobenzene); and Robust Summaries and Repository of Knowledge for CAS No. 87-61-6 (1,2,3-trichlorobenzene). This document differs from the one submitted to the EPA on March 14, 2002, in that it contains additions and improvements and the following changes to the robust summaries, category development, and test plan:

Health Effects: Reproductive/Developmental Toxicity

Reproductive Toxicity: Additional data have been added to the robust summary for 1,2-dichlorobenzene to explain that the decreased pup survival only occurred in one litter, and if this litter was dropped from the calculation, overall pup survival was not affected by treatment. Since the authors concluded that this was not due to treatment with the test material, this point was removed from the test plan. Additional results from the studies have been added to the summary for 1,4-dichlorobenzene and the test plan that support our conclusion that these materials are not reproductive toxicants, but are fetotoxic.

Developmental Toxicity: In the first draft of the test plan and summaries, the NOAELs listed were for teratogenicity and maternal toxicity. In the new drafts of the documents, the NOAELs for fetotoxicity have been added for each study. It is agreed that the skeletal and soft tissue variations are indicative of slight fetotoxicity. This point has been added to the test plan.

Note: The NOAELs in the summaries and test plan have been rectified, and the designation that the John study was an abstract has been removed from the test plan.

Ecological Effects

The results of ECOSAR modeling for fish, aquatic invertebrates and algae have been added to the test plan and robust summaries of all category members.

Physiochemical Properties

Comments were received requesting additional information on the methods used for determining melting points, boiling points, vapor pressure, and water solubility, in particular, whether these were measured values or calculated values. In response, further details have been given when available. The following should be noted:

- Some summaries for these endpoints came from the European Chemical Bureau data sets, and these have been incorporated into the category members summary sets intact. The European summaries do not give details or reference citations about methodology.

- Some physiochemical data were taken from manufacturers' material safety data sheets, and the original sources for some of these data cannot always be identified or documented. It is likely that in these cases the actual measurements were conducted decades ago, or the data were taken from reliable secondary sources, such as the Merck Index, Ullmann's Encyclopedia of Industrial Chemistry, Kirk Othmer Encyclopedia of Chemical Technology, and/or the CRC Handbook of Chemistry and Physics. Re-examination of the values given in the robust summary sets show them to be consistent with values given in the above-named reference books, which are recognized data sources and references for physiochemical data according to the high production volume chemical guidelines.

- Finally, chlorobenzenes are some of the oldest organic substances known and were characterized for their physiochemical properties at a time that predated modeling methodology, and the data therefore are almost certainly measured and not calculated.

Boiling points and vapor pressures, for example, are well established, since these substances are routinely purified by distillation. By contrast, determinations of Log Kow for these substances have been done more recently and are model calculations. The inputs to these models have been added to the summaries.

Environmental Fate

Biodegradation: Data for this endpoint came from a previous IUCLID document created by the European Chemicals Bureau. According to guidelines, these data should not be altered when reproduced in new IUCLID documents. A remark was added that the test material was obviously 1,3-dichlorobenzene based on information stated in the summary.

Fugacity: Input values for all calculations have been added.

Health Effects

Acute Toxicity: Additional information about monochlorobenzene, 1,2-dichlorobenzene, and 1,3-dichlorobenzene test material purity, study design, and statistical methods was added to the summaries if available.

- Monochlorobenzene: The total number of rats used in the oral Younger studies was 5/group (2-3 males and 2-3 females). The summary has been rewritten to stress this fact. Five rats/group is sufficient for acute studies. Therefore, this study was assigned a reliability rating of 1. The Younger dermal study only used 3 rats and two doses. The reliability rating has been changed to 4 (since the number of animals was not sufficient) in the summary and test plan.

- 1,2-Dichlorobenzene: The exact number of animals used in the French inhalation studies for 1,2-dichlorobenzene was not available because the exact concentrations tested were not listed and the only the number of animals/group was listed. The numbers of animals in these groups were more than sufficient to assess the effect of each concentration (at least 12/concentration). The exposure time was 6 hours. Details about

the statistical methods have been added.

Additional Changes

The word "sacrifice" was removed from all summaries and replaced with either "terminate" or "euthanize".

The test conditions for the chromosomal aberration and sister chromatid exchange study for 1,4-dichlorobenzene (which appears in the robust summary set for 1,3-dichlorobenzene and is reference 15) have been rewritten due to the fact that the original robust summaries were written from a copy of the reference that had a missing page. This page contained critical information that was missing from the original robust summaries.

With these additional comments and clarifications made in response to EPA's questions and remarks, and the resubmission of the entire edited final HPV document, CPA has met its obligation in the EPA HPV Challenge Program.

Please contact me at (202) 721-4145 if there are any questions relating to this submission.

Sincerely,

Edward W. Kordoski, MBA, Ph.D.

Executive Director, Chlorobenzene Producers Association

cc: CPA Group Members

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CPA EPA HPV Final Document for Chlorobenzene 1-29-2(

CPA EPA HPV Chlorobenzenes Final Category Test Plan 1-29-2

CPA EPA HPV Final Document for 1,2 - Dichlorobenzene 1-29-2

CPA EPA HPV Final Document for 1,2,3 - Trichlorobenzene 1-29-2

CPA EPA HPV Final Document for 1,3 - Dichlorobenzene 1-29-2